Assembly Bill No. 556

CHAPTER 796

An act to amend Sections 109890, 109925, 110025, 110110, 110405, 111330, 111355, 111490, and 111610 of, to add Section 110111 to, and to repeal Sections 110305, 111350, 111405, and 111410 of, the Health and Safety Code, relating to food and drugs.

[Approved by Governor September 28, 2000. Filed with Secretary of State September 28, 2000.]

LEGISLATIVE COUNSEL'S DIGEST

AB 556, Davis. Drugs and devices: conformity to federal law.

Existing law, the Sherman Food, Drug, and Cosmetic Law, contains provisions regarding the designation, labeling, and advertisement of drugs and devices, as defined, for sale in the state. Under existing law, a violation of any of these provisions is punishable as a misdemeanor.

This bill would conform these provisions to the federal Food and Drug Administration Modernization Act of 1997 with regard to the regulation of products subject to the federal Food and Drug Administration jurisdiction.

Since a violation of the provisions applicable to the sale of drugs and devices is a crime, this bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

The people of the State of California do enact as follows:

SECTION 1. Section 109890 of the Health and Safety Code is amended to read:

109890. ''Antibiotic drug'' means any drug , except drugs for use in animals other than humans, composed in whole or in part of any form of penicillin, streptomycin, chlortetracycline chloramphenicol, bacitracin, or any other drug intended for human use containing any quantity of any chemical substance that is produced by micro-organisms, and that has the capacity to inhibit or destroy micro-organisms in dilute solution, including a chemically synthesized equivalent, or any derivative thereof.

SEC. 2. Section 109925 of the Health and Safety Code is amended to read:

109925. ''Drug'' means any of the following:

(a) Any article recognized in an official compendium.

(b) Any article used or intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in human beings or any other animal.

(c) Any article other than food, that is used or intended to affect the structure or any function of the body of human beings or any other animal.

(d) Any article used or intended for use as a component of any article designated in subdivision (a), (b), or (c) of this section.

The term ''drug'' does not include any device.

Any food for which a claim (as described in Sections 403(r)(1)(B) (21 U.S.C. Sec. 343(r)(1)(B)) and 403(r)(3) (21 U.S.C. Sec. 343(r)(3)) or Sections 403(r)(1)(B) (21 U.S.C. Sec. 343(r)(1)(B)) and 403(r)(5)(D) (21 U.S.C. Sec. 343(r)(5)(D)) of the federal act), is made in accordance with the requirements set forth in Section 403(r) (21 U.S.C. Sec. 343(r)) of the federal act, is not a drug under subdivision (b) solely because the label or labeling contains such a claim.

SEC. 3. Section 110025 of the Health and Safety Code is amended to read:

110025. (a) ''Substantial evidence'' means evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug or device involved, on the basis that it could be fairly and responsibly concluded by the experts that the drug or device will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling, proposed labeling, or advertising of any drug or device.

(b) If the department determines, based on relevant science, that data from one adequate and well-controlled clinical investigation, and confirming evidence, obtained prior to or after the investigation, sufficiently establish effectiveness, then the department may consider that data and evidence, to constitute substantial evidence for purposes of the preceding sentence.

SEC. 4. Section 110110 of the Health and Safety Code is amended to read:

110110. (a) All regulations relating to (1) new drug applications, except for abbreviated new drug applications, adopted pursuant to Section 505 of the federal act (21 U.S.C. Sec. 355), (2) applications for premarket approval of new devices, adopted pursuant to Section 515 of the federal act (21 U.S.C. Sec. 360e), (3) postmarketing reports, recordkeeping, and other postapproval requirements for approved new drug applications or approved new device premarket approval

applications, adopted pursuant to the federal act, that are in effect on January 1, 1993, or that are adopted on or after that date, shall be the new drug and new device application regulations of this state.

(b) The department may, by regulation, adopt any new drug or new device application regulation that it determines is necessary for the administration and enforcement of this part, whether or not the regulation is in accordance with the regulations adopted pursuant to the federal act.

SEC. 5. Section 110305 of the Health and Safety Code is repealed.

SEC. 6. Section 110405 of the Health and Safety Code is amended to read:

110405. An advertisement that is not unlawful under Section 110390 is not unlawful under Section 110403 if it is either one of the following:

(a) Disseminated only to members of the medical, dental, pharmaceutical, or veterinary professions, or appears only in the scientific periodicals of these professions, or is disseminated only for the purpose of public health education by persons not commercially interested, directly or indirectly, in the sale of drugs or devices.

(b) An advertisement that a drug or device has a specific curative or therapeutic effect on a condition, disorder, or disease listed in Section 110403 if the drug or device is approved or cleared for marketing for that specific curative or therapeutic effect through any of the following means:

(1) A new drug application approved pursuant to Section 111500, or Section 505 of the federal act (21 U.S.C. Sec. 355).

(2) An abbreviated new drug application approved pursuant to Section 505 of the federal act (21 U.S.C. Sec. 355).

(3) A licensed biological product pursuant to Section 351 of the Public Health Service Act (42 U.S.C. Sec. 262).

(4) A nonprescription drug that meets the requirements of Part 330 of Title 21 of the Code of Federal Regulations.

(5) A new animal drug application approved under Section 512 of the federal act (21 U.S.C. Sec. 360b).

(6) An abbreviated new animal drug application approved pursuant to Section 512 of the federal act (21 U.S.C. Sec. 360b).

(7) A new device application approved pursuant to Section 111550.

(8) A device premarket approval application approved under Section 515 of the federal act (21 U.S.C. Sec. 360e).

(9) A determination of substantial equivalence for a device pursuant to Section 513(f)(1) of the federal act (21 U.S.C. Sec. 360c(i)).

SEC. 7. Section 111330 of the Health and Safety Code is amended to read:

111330. Any drug or device is misbranded if its labeling is false or misleading in any particular.

SEC. 8. Section 111350 of the Health and Safety Code is repealed.

SEC. 9. Section 111355 of the Health and Safety Code is amended to read:

111355. (a) Any drug is misbranded unless its label bears, to the exclusion of any other nonproprietary name except the applicable, systematic chemical name or the chemical formula, all of the following information:

(1) The established name of the drug, if any.

(2) If it is fabricated from two or more ingredients, the established name and quantity of each active ingredient, including the kind and quantity or proportion of any alcohol, and also including, whether active or not, the established name and quantity or proportion of any bromides, ether, chloroform, acetanilide, acetophenetidin, antipyrine, atropine, hyoscine, hyoscyamine, codeine, arsenic, digitalis, digitalis glycosides, mercury, ouabain, strophanthin, strychnine, barbituric acid, or any derivative or preparation of any substances contained therein.

(3) For nonprescription drugs, the quantity or proportion of each active ingredient and the established name of each inactive ingredient in accordance with Sections 502(e)(1)(A)(ii) and (iii) of the federal act (21 U.S.C. 352(e)(1)(A)(ii) and (iii)).

(b) The requirement for stating the quantity of the active ingredients of any drug, including the quantity or proportion of any alcohol, and also including, whether active or not, the quantity or proportion of any bromides, ether, chloroform, acetanilide, acetophenetidin, antipyrine, atropine, hyoscine, hyoscyamine, codeine, arsenic, digitalis, digitalis glycosides, mercury, ouabain, strophanthin, strychnine, barbituric acid, or any derivative or preparation of any substances contained therein, shall apply to all drugs, including prescription drugs and nonprescription drugs. However, the requirement for declaration of quantity shall not apply to nonprescription drugs that are also cosmetics, as defined in Section 201(i) of the federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 321(i)) and that are labeled in compliance with federal labeling requirements concerning declaration of ingredients including active ingredients and also the quantity and proportion of any alcohol, except that the quantity or proportion of the following ingredients, whether active or not, shall be declared: bromides, ether, chloroform, acetanilide, acetophenetidin, antipyrine, atropine, hyoscine, hyoscyamine, codeine, arsenic, digitalis, digitalis glycosides, mercury, ouabain, strophanthin, strychnine, barbituric acid, or any derivative or preparation of any substances contained therein. The department may exempt any nonprescription drug from the requirement of stating the quantity of the active ingredients, other than those specifically named in this subdivision, upon a showing by the applicant through evidence satisfactory to the department that the granting of the exemption will not endanger the public health.

For any prescription drug the established name of the drug or ingredient, as the case may be, on the label and on any labeling on which a name for the drug or ingredient is used shall be printed prominently and in type at least half as large as that used thereon for any proprietary name or designation for the drug or ingredient.

The changes made in this section by Chapter 943 of the Statutes of 1978 shall not apply to any drug shipped by a manufacturer or packer to a retailer or wholesaler before January 1, 1980. Any such drugs so shipped shall comply with this section on and after January 1, 1981.

SEC. 10. Section 111405 of the Health and Safety Code is repealed.

SEC. 11. Section 111410 of the Health and Safety Code is repealed.

SEC. 12. Section 111490 of the Health and Safety Code is amended to read:

111490. (a) A drug or device that is subject to Section 111470 is misbranded if at any time prior to dispensing, its label fails to bear the statement ''Caution: federal law prohibits dispensing without prescription,'' or ''Caution: state law prohibits dispensing without prescription,'' or ''R_x only.'' A drug or device to which Section 111470 does not apply is misbranded if at any time prior to dispensing its label bears the caution statement or ''R_x only'' quoted in the preceding sentence.

(b) A device that is subject to Section 111470 is misbranded if, at any time prior to dispensing, its label fails to bear the statement ''Caution: federal law restricts this device to sale by or on the order of a _____ ,'' the blank to be filled in with the designation of the practitioner licensed to use or order use of the device. A device to which Section 111470 does not apply is misbranded if, at any time prior to dispensing, its label bears the caution statement quoted in the preceding sentence.

SEC. 13. Section 111610 of the Health and Safety Code is amended to read:

111610. Section 111550 does not apply to any of the following:

(a) A drug or device that is sold in this state, or introduced into interstate commerce, at any time prior to the enactment of the federal act, if its labeling and advertising contained the same representations concerning the conditions of its use.

(b) Any drug that is licensed under the Public Health Service Act of July 1, 1944 (58 Stats. 682, as amended; 42 U.S.C. Sec. 201 et seq.) or under the eighth paragraph of the heading of Bureau of Animal Industry of the act of March 4, 1913 (37 Stat. 832–833; 21 U.S.C. Sec. 151 et seq.), commonly known as the ''Virus-Serum-Toxin Act.''

SEC. 14. Section 110111 is added to the Health and Safety Code, to read:

110111. All nonprescription drug regulations and any amendments to those regulations adopted pursuant to the federal

act, that are in effect on January 1, 2000, or that are adopted on or after that date, shall be the nonprescription drug regulations of the state. The department may adopt any nonprescription drug regulation it deems necessary for the administration and enforcement of this part, provided that the regulation is not different from, or in addition to, any requirement for nonprescription drugs pursuant to Section 751 (21 U.S.C. Sec. 379r) of the federal act.

SEC. 15. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

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